

We Claim:

1. A method for assessing risk of prostate cancer in a patient which comprises measuring levels of both Cln101 and Prostate Specific Antigen (PSA) in the patient,
5 analyzing a risk associated with the level of PSA and a risk associated with the level of Cln101, and using the combined risks to assess the risk of prostate cancer in the patient.
2. The method of claim 1 wherein the measuring of PSA and Cln101 levels are done simultaneously.
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3. The method of claim 1 wherein the measuring of PSA and Cln101 are done sequentially.
4. The method of claim 1 wherein the respective levels of PSA and Cln101 are based
15 on dividing a patient population dataset into borderline levels of PSA and elevated levels of Cln101 and a patient having both borderline PSA and high Cln101 levels is indicative of heightened risk of prostate cancer.
5. The method of claim 4 wherein the borderline levels of PSA are between about 2
20 ng/mL and about 10 ng/mL.
6. The method of claim 4 wherein the borderline levels of PSA are between about 4 ng/mL and about 10 ng/mL.
- 25 7. The method of claim 4 wherein the borderline levels of PSA are between about 2 ng/mL and about 4 ng/mL.
8. A method for assessing risk of ovarian cancer in a patient which comprises measuring levels of Cln101 in the patient to assess the risk of ovarian cancer in the patient.
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9. A method for assessing risk of ovarian cancer in a patient which comprises measuring levels of both Cln101 and CA125 in the patient, analyzing a risk associated with the level of CA125 and a risk associated with the level of Cln101, and using the combined risks to assess the risk of ovarian cancer in the patient.
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10. The method of claim 9 wherein the measuring of CA125 and Cln101 levels are done simultaneously.
11. The method of claim 9 wherein the measuring of CA125 and Cln101 are done sequentially.
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12. The method of claim 9 wherein the ovarian cancer is stage 1 or stage 2 ovarian cancer.
13. The method of claim 9 wherein the respective levels of CA125 and Cln101 are based on dividing a patient population dataset into CA125 levels not indicative of cancer and elevated levels of Cln101 and a patient having both CA125 levels indicative of cancer and high Cln101 levels is indicative of heightened risk of ovarian cancer.
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14. The method of claim 13 wherein the CA125 levels not indicative of cancer are below about 30 U/ml.
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15. The method of claim 13 wherein the CA125 levels not indicative of cancer are between about 30 U/ml and about 40 U/ml.
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16. The method of claim 13 wherein the CA125 levels not indicative of cancer are between about 30 U/ml and about 35 U/ml.
17. A method for treating a subject with heightened risk of a prostate cancer, comprising: selecting a subject who has borderline levels of Prostate Specific Antigen
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(PSA) and elevated levels of Cln101 and treating the subject with a therapy selected from the group consisting of surgery, radiation therapy, hormone therapy immunotherapy or chemotherapy so as to alleviate the heightened risk of prostate cancer in the subject.

- 5 18. A method for treating a subject with heightened risk of a ovarian cancer, comprising: selecting a subject who has elevated levels of Cln101 and treating the subject with a therapy selected from the group consisting of surgery, radiation therapy, hormone therapy, immunotherapy or chemotherapy so as to alleviate the heightened risk of ovarian cancer in the subject.

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19. A method for treating a subject with heightened risk of a ovarian cancer, comprising: selecting a subject who has levels of CA125 not indicative of cancer and elevated levels of Cln101 and treating the subject with a therapy selected from the group consisting of surgery, radiation therapy, hormone therapy, immunotherapy or
15 chemotherapy so as to alleviate the heightened risk of ovarian cancer in the subject.

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20. A kit for diagnosing a patient's susceptibility to prostate cancer comprising both a suitable assay for measuring Cln101 levels and a suitable assay for measuring Prostate Specific Antigen (PSA) levels wherein the levels of both PSA and Cln101 are determined.

21. A kit for diagnosing a patient's susceptibility to ovarian cancer comprising a suitable assay for measuring Cln101 levels wherein the levels of Cln101 are determined.

22. A kit for diagnosing a patient's susceptibility to ovarian cancer comprising both a
25 suitable assay for measuring Cln101 levels and a suitable assay for measuring CA125 levels wherein the levels of both CA125 and Cln101 are determined.

23. The kit of claim 20, 21 or 22 further comprising antibodies which bind the same
30 epitopes as those produced by a hybridoma selected from the group consisting of ATCC accession number PTA-5877 and PTA-5876.

24. An isolated Cln101 antibody that binds to mammalian Cln101 in vivo or in vitro.
25. The antibody of claim 24 which internalizes upon binding to Cln101 on a
5 mammalian cell in vivo.
26. The antibody of claim 24 or claim 25 which is a monoclonal antibody.
27. The antibody of claim 24 or claim 25 which is an antibody fragment.
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28. The antibody of claim 24 or claim 25 which is a chimeric or a humanized antibody.
29. The antibody of claim 26 which is produced by a hybridoma selected from the
15 group consisting of American Type Culture Collection accession number PTA-5877 and PTA-5876.
30. The antibody of claim 26, wherein the antibody competes for binding to the
20 same epitope as the epitope bound by the monoclonal antibody produced by a hybridoma selected from the group consisting of ATCC accession number PTA-5877 and PTA-5876.
31. The antibody of claim 26 which is conjugated to a growth inhibitory agent.
32. The antibody of claim 26 which is conjugated to a cytotoxic agent.
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33. The antibody of claim 32 wherein the cytotoxic agent is selected from the group consisting of toxins, antibiotics, radioactive isotopes and nucleolytic enzymes.
34. The antibody of claim 33 wherein the cytotoxic agent is a toxin.
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35. The antibody of claim 34, wherein the toxin is selected from the group consisting of ricin, saponin, maytansinoid and calicheamicin.

36. The antibody of claim 35, wherein the toxin is a maytansinoid.
37. The antibody of claim 26, wherein the mammalian Cln101 is produced by a
5 cancer cell.
38. An anti-Cln101 monoclonal antibody that selectively binds a Cln101-
expressing cell.
- 10 39. An anti-Cln101 monoclonal antibody that inhibits the growth of Cln101-
expressing cancer cells in vivo.
40. The antibody of claim 39 which is a humanized or human antibody.
- 15 41. The antibody of claim 40 which is produced in bacteria.
42. The antibody of claim 38, which is a humanized form of an anti-Cln101
antibody produced by a hybridoma selected from the group consisting of ATCC accession
number PTA-5877 and PTA-5876.
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43. The antibody of claim 39, wherein the cancer cells are from a cancer selected
from the group consisting of prostate and ovarian cancer.
44. The antibody of claim 43, wherein the cancer is prostate or ovarian cancer.
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45. A cell that produces the antibody of claim 26.
46. The cell of claim 45, wherein the cell is selected from the group consisting of
hybridoma cells deposited under American Type Culture Collection accession number
30 PTA-5877 and PTA-5876.

47. A method of producing the antibody of claim 26 comprising culturing an appropriate cell and recovering the antibody from the cell culture.
- 5 48. A composition comprising the antibody of claim 26 or claim 38, and a carrier.
49. The composition of claim 48, wherein the antibody is conjugated to a cytotoxic agent.
- 10 50. The composition of claim 49, wherein the cytotoxic agent is a maytansinoid.
51. The composition of claim 48, wherein the antibody is a human or humanized antibody and the carrier is a pharmaceutical carrier.
- 15 52. The composition of claim 51, wherein the humanized antibody is a humanized form of an anti-Cln101 antibody produced by a hybridoma selected from the group consisting of ATCC accession number PTA-5877 and PTA-5876.
- 20 53. A method of killing a Cln101-expressing cancer cell, comprising contacting the cancer cell with the antibody of claim 24 or claim 25, thereby killing the cancer cell.
54. The method of claim 53, wherein the cancer cell is selected from the group consisting of prostate and ovarian cancer cells.
- 25 55. The method of claim 54, wherein the cancer cell is a prostate or ovarian cancer cell.
56. The method of claim 55, wherein the ovarian cancer is ovarian serous adenocarcinoma.
- 30 57. The method of claim 54, wherein the cancer cell is from metastatic prostate or ovarian cancer.

58. The method of claim 53, wherein the antibody is an antibody fragment.
59. The method of claim 53 wherein the antibody is a humanized antibody.
- 5 60. The method of claim 53, wherein the antibody is conjugated to a cytotoxic agent.
61. The method of claim 60, wherein the cytotoxic agent is a toxin selected from the group consisting of maytansinoid, ricin, saporin and calicheamicin.
- 10 62. The method of claim 53, wherein the antibody is a humanized form of the antibody produced by a hybridoma selected from the group consisting of ATCC accession number PTA-5877 and PTA-5876.
- 15 63. The method of claim 60, wherein the cytotoxic agent is a radioactive isotope.
64. A method of alleviating a Cln101-expressing cancer in a mammal, comprising administering a therapeutically effective amount of the antibody of claim 38 to the mammal.
- 20 65. The method of claim 65, wherein the cancer is selected from the group consisting of prostate and ovarian cancer.
66. The method of claim 65 wherein the ovarian cancer is ovarian serous adenocarcinoma cancer.
- 25 67. The method of claim 64, wherein the antibody is a humanized antibody.
68. The method of claim 64, wherein the antibody is conjugated to a cytotoxic agent.
- 30 69. The method of claim 63, wherein the cytotoxic agent is a maytansinoid.

70. The method of claim 69, wherein the antibody is administered in conjunction with at least one chemotherapeutic agent.
- 5 71. The method of claim 70 wherein the chemotherapeutic agent is paclitaxel or derivatives thereof.
72. An article of manufacture comprising a container and a composition contained therein, wherein the composition comprises an antibody of claim 26.
- 10 73. The article of manufacture of claim 72 further comprising a package insert indicating that the composition can be used to treat prostate or ovarian cancer.
74. A method for determining if cells in a sample express Cln101 comprising
- 15 (a.) contacting a sample of cells with an Cln101 antibody of claim 26 under conditions suitable for specific binding of the Cln101 antibody to Cln101 and
- (b.) determining the level of binding of the antibody to cells in the sample, or the level of Cln101 antibody internalization by cells in said
- 20 sample,
- wherein Cln101 antibody binding to cells in the sample or internalization of the Cln101 antibody by cells in the sample indicate cells in the sample express Cln101.
75. The method of claim 74 wherein said sample of cells are contacted with an
- 25 antibody produced by a hybridoma selected from the group of consisting of ATCC accession number PTA-5877 and PTA-5876.
76. The method of claim 74 wherein said sample of cells is from a subject who has a cancer, is suspected of having a cancer or who may have a predisposition for developing
- 30 cancer.
77. The method of claim 76 wherein the cancer is a prostate or ovarian cancer.

78. The method of claim 74 wherein said antibody is a labeled antibody.

79. A method for detecting Cln101 overexpression in a test cell sample,
5 comprising:

- (a.) combining a test cell sample with an Cln101 antibody of claim
26 under conditions suitable for specific binding of Cln101 to Cln101
expressed by cells in said test sample
- (b) determining the level of binding of the Cln101 antibody to the cells in
10 the test sample,
- (c) comparing the level of Cln101 antibody bound to the cells in step (b) to
the level of Cln101 antibody binding to cells in a control cell sample,
wherein an increase in the binding of the Cln101 antibody in the test cell sample as
compared to the control is indicative of Cln101 overexpression by cells in the test cell
15 sample.

80. The method of claim 79 wherein the test cell sample is a cancer cell sample.

81. The method of claim 80 wherein the cancer cell sample is of a prostate or
20 ovarian cancer.

82. The method of claim 81 wherein the ovarian or prostate cancer is ovarian
serous adenocarcinoma or metastatic cancer.

25 83. The method of claim 80 wherein the control is a sample of adjacent normal
tissue.

84. A method for detecting Cln101 overexpression in a subject in need thereof
comprising,

- 30 (a.) combining a bodily fluid sample of a subject with an Cln101
antibody of claim 26 under conditions suitable for specific binding of the
Cln101 antibody to Cln101 in said bodily fluid sample

- (b.) determining the level of Cln101 in the bodily fluid sample,
(c.) comparing the level of Cln101 determined in step b to the
level of Cln101 in a control,

5 wherein an increase in the level of Cln101 in the bodily fluid sample from the
subject as compared to the control is indicative of Cln101 overexpression in the subject.

85. The method of claim 84 wherein the subject has cancer.

10 86. The method of claim 85 wherein the subject has prostate or ovarian cancer.

87. The method of claim 86 wherein the ovarian or prostate cancer is ovarian
serous adenocarcinoma or metastatic cancer.

15 88. The method of claim 84 wherein the control is a bodily fluid sample from a
subject without a cancer overexpressing Cln101.

89. A screening method for antibodies that bind to an epitope which is bound by an
antibody of claim 26 comprising,

- 20 (a.) combining an Cln101-containing sample with a test antibody
and an antibody of claim 26 to form a mixture ,
(b.) determining the level of Cln101 antibody bound to Cln101 in
the mixture and
(c.) comparing the level of Cln101 antibody bound in the mixture
of step (a) to a control mixture,

25 wherein the level of Cln101 antibody binding to Cln101 in the mixture as
compared to the control is indicative of the test antibody's binding to an epitope that is
bound by the anti-Cln101 antibody of claim 26.

30 90. The screening method of claim 89 wherein the level of Cln101 antibody bound
to Cln101 is determined by ELISA. .

91. The screening method of claim 89 wherein the control is a mixture of Cln101, Cln101 antibody of claim 26 and an antibody known to bind the epitope bound by the Cln101 antibody of claim 26.
- 5 92. The screening method of claim 89 wherein the anti-Cln101 antibody is labeled.
93. The screening method of claim 92 wherein the Cln101 is bound to a solid support.
- 10 94. The screening method of claim 93 wherein the solid support is a sepharose bead.